General

Guideline Title

UK national guideline for the management of bacterial vaginosis 2012.

Bibliographic Source(s)

Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH). National guideline for the management of bacterial vaginosis. London (UK): British Association for Sexual Health and HIV (BASHH); 2012. 15 p. [43 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previously released version: Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH). National guideline for the management of bacterial vaginosis. London (UK): British Association for Sexual Health and HIV (BASHH); 2006. 14 p. [40 references]

Recommendations

Major Recommendations

Levels of evidence (I-IV) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Diagnosis

Two approaches are available:

- Amsel criteria. At least three of the four criteria are present for the diagnosis to be confirmed.
    1. Thin, white, homogeneous discharge
    2. Clue cells on microscopy of wet mount
    3. pH of vaginal fluid >4.5
    4. Release of a fishy odour on adding alkali (10% potassium hydroxide [KOH])
- A Gram stained vaginal smear, evaluated with the Hay/Ison criteria or the Nugent criteria.
  The Hay/Ison criteria are defined as follows:
    - Grade 1 (Normal): Lactobacillus morphotypes predominate
    - Grade 2 (Intermediate): Mixed flora with some Lactobacilli present, but Gardnerella or Mobiluncus morphotypes also present
    - Grade 3 (Bacterial vaginosis [BV]): Predominantly Gardnerella and/or Mobiluncus morphotypes. Few or absent Lactobacilli

  There are additional grades which have not been correlated with clinical features: grade 0 No bacteria present; grade 4 Gram-positive cocci predominate.

The Nugent score is derived from estimating the relative proportions of bacterial morphotypes to give a score between 0 and 10. A score of <4 is normal, 4 to 6 is intermediate, and >6 is BV.

The Bacterial Special Interest group of British Association for Sexual Health and HIV (BASHH) recommend using the Hay/Ison criteria in Genitourinary medicine clinics (C).

- Isolation of *Gardnerella vaginalis* cannot be used to diagnose BV because it can be cultured from the vagina of more than 50% normal women (IIa).
  BV may co-exist with other causes of abnormal discharge such as candidiasis, trichomoniasis, and cervicitis.

Management

General Advice

Patients should be advised to avoid vaginal douching, use of shower gel, and use of antiseptic agents or shampoo in the bath (C).

Treatment

Treatment is indicated for:

- Symptomatic women (A)
- Women undergoing some surgical procedures (A)
- Women who do not volunteer symptoms may elect to take treatment if offered. They may report a beneficial change in their discharge following treatment. (C)

Recommended Regimens

- Metronidazole 400 mg twice daily for 5-7 days (A)
  or
- Metronidazole 2 g single dose (A)
  or
- Intravaginal metronidazole gel (0.75%) once daily for 5 days (A
  or
- Intravaginal clindamycin cream (2%) once daily for 7 days (A)

Alternative Regimens

- Tinidazole 2 g single dose (A)
  or
- Clindamycin 300 mg twice daily for 7 days (A)

Caution

- With metronidazole treatment alcohol should be avoided because of the possibility of a disulfiram-like action. There are no data on the risks from consuming alcohol with intravaginal metronidazole gel, but it is not recommended at present.
- Clindamycin cream can weaken condoms, which should not be used during such treatment. Pseudomembranous colitis has been reported with both oral clindamycin and clindamycin cream.

Allergy

Allergy to metronidazole is uncommon. Use 2% clindamycin cream for metronidazole allergic women.

Pregnancy and Breast Feeding

Meta-analyses have concluded that there is no evidence of teratogenicity from the use of metronidazole in women during the first trimester of pregnancy (Ia).

The results of clinical trials investigating the value of screening for and treating BV in pregnancy have been conflicting. It is therefore difficult to

make firm recommendations. A detailed discussion of trials in pregnancy is outside the scope of this guideline. The most recent Cochrane review concluded that there is little evidence that screening and treating all pregnant women with asymptomatic BV will prevent preterm birth and its consequences. However there is some suggestion that treatment before 20 weeks gestation may reduce the risk. In conclusion:

- Symptomatic pregnant women should be treated in the usual way (B).
- There is insufficient evidence to recommend routine treatment of asymptomatic pregnant women who attend a genitourinary clinic and are found to have BV.
- Women with additional risk factors for preterm birth may benefit from treatment before 20 week gestation.

Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breast feeding. Small amounts of clindamycin enter breast milk. It is prudent therefore to use an intravaginal treatment for lactating women (C).

Termination of Pregnancy (TOP)

Three studies have investigated whether antibiotics can reduce the rate of infectious morbidity in women with BV, following termination of pregnancy. A Scandinavian study of 231 women demonstrated a reduction in post-TOP infection by treating BV with oral metronidazole before termination (Ib). Another demonstrated a reduction in infective complications following the use of clindamycin cream (Ib). A United Kingdom study of 273 women again found a reduction in post-operative upper genital tract infection from 16% to 8.5%, but did not quite reach statistical significance. There are no data on the effectiveness of treatment administered at the time of TOP.

- These studies support screening for and treating BV with either metronidazole or clindamycin cream, to reduce the incidence of subsequent endometritis and pelvic inflammatory disease (PID) (Ia).

Human Immunodeficiency Virus (HIV) Infection

Women with HIV have not been shown to respond differently to treatment for BV than those without. In an as yet unpublished study BV was a risk factor for female to male HIV transmission so there may be rationale for attempting to suppress BV or treat recurrence rapidly in discordant couples.

Sexual Partners

- No reduction in relapse rate was reported from two studies in which male partners of women with bacterial vaginosis were treated with metronidazole, one study of tinidazole, and one of clindamycin (Ib). Routine screening and treatment of male partners are therefore not indicated.
- Two studies reported a high incidence of bacterial vaginosis in female partners of lesbians with BV (II). No study has investigated the value of treating partners of lesbians simultaneously.

Follow Up

A test of cure is not required if symptoms resolve.

Recurrent BV

Several published studies have evaluated treatments for women with frequent recurrences of BV.

- Suppressive 0.75% metronidazole vaginal gel. In one placebo controlled randomised trial 0.75% metronidazole vaginal gel twice a week for 16 weeks was superior to placebo with 70% of women being relapse-free compared to 39% in the placebo group. However, only 34% of patients remained cumulatively free of recurrence 12 weeks after stopping treatment, compared to 22% of controls. There was an excess of vulvovaginal candidosis in those receiving metronidazole: 43% compared to 21%.
- Probiotic therapy. A double blind randomised controlled trial of probiotic lactobacilli applied daily on days 1-7 and 15-21, in 117 women showed significantly lower recurrence rates over the ensuing two months in women with at least two episodes of BV in the preceding year: BV (15.8% [9/57 women] versus 45.0% [27/60 women]).
- Antibiotics and probiotic therapy. A Swedish study of 76 women whose BV resolved following a course of clindamycin cream were randomised to receive human lactobacilli or placebo. At the end of the study, 65% (24/37) of the lactobacilli treated women remained BV-free compared to 46% (18/39) of the placebo treated women.
- Lactic acid gel and acetic acid gel (the latter is no longer available in the UK) have not been evaluated adequately in well-designed RCTs.

General Advice

- A detailed explanation of BV should be provided, reinforced with clear and accurate written information (C [IV]).

When giving information to patients, the clinician should consider the following:

- An explanation of what treatment is being given, how to take it, and its possible adverse effects
- That following treatment BV can recur, but will respond to standard treatments
- Partners do not need to be screened routinely. Some clinicians recommend screening male partners of women with recurrent BV for urethritis, as it was associated with BV in one study.

Further Investigation

Routine sexually-transmitted infection (STI) screening should be offered in accordance with current testing guidelines.

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grades of Recommendation

A (Evidence Levels Ia, Ib)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Bacterial vaginosis

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Infectious Diseases

Obstetrics and Gynecology

Urology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To offer recommendations on diagnosis, treatment regimens, and health promotion principles needed for the effective management of bacterial vaginosis (BV) covering the management of the initial presentation and recurrence

Target Population

Women in the United Kingdom with bacterial vaginosis (BV)

Note: The guideline is aimed primarily at people aged 16 years or older (see specific guidelines for those under 16).

Interventions and Practices Considered

Diagnosis/Evaluation

1. Evaluation of vaginal discharge using the Amsel criteria
2. Microscopic assessment of a gram stained vaginal smear, evaluated with the Hay/Ison or Nugent criteria

Treatment/Management

1. General advice to patients
2. Treatment
    - Metronidazole, oral or intravaginal gel
    - Clindamycin, oral or intravaginal cream
    - Tinidazole, oral
3. Prevention of relapse (the following are considered, but no recommendations are made)
    - Metronidazole, intravaginal gel
    - Probiotic therapy
    - Antibiotics with probiotic therapy
    - Lactic acid gel and acetic acid gel (the latter is no longer available in the UK)
4. Screening for and treating bacterial vaginosis with either metronidazole or clindamycin cream to reduce the incidence of subsequent endometritis and pelvic inflammatory disease in women undergoing termination of pregnancy

5. Sexual partner management
6. Follow-up

Major Outcomes Considered

- Cure rate
- Relapse rate

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Four reference sources were used to provide a comprehensive basis for the guideline:

1. Medline and Embase Search
    a. 1948 – Aug 2011
    The search strategy comprised the following terms in the title or abstract: 'bacterial vaginosis'. 5,052 citations were identified.
2. 2010 Centers for Disease Control and Prevention (CDC) Sexually-Transmitted Disease (STD) Treatment Guidelines (www.cdc.gov/std/)
3. 2011 European (International Union against Sexually Transmitted Infections [IUSTI]/World Health Organization [WHO]) Guideline on the Management of Vaginal Discharge
4. Cochrane Collaboration Databases (www.cochrane.org)

Article titles and abstracts were reviewed and if relevant the full text article obtained. Priority was given to randomised controlled trial and systematic review evidence.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Priority was given to randomised controlled trial and systematic review evidence, and recommendations made and graded on the basis of best available evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline development is undertaken by a multi-disciplinary writing committee with membership determined in a transparent manner. The chair is chosen by the Clinical Effectiveness Group (CEG). The CEG lead then discusses with the chair what suggestions they might have for members from other disciplines. The additional members of the group are then invited by the CEG. Writing committee membership includes relevant professional groups (for example genitourinary medicine physicians, nurses, health advisors, pharmacists, microbiologists and other professionals from allied specialities as appropriate) and when relevant this will involve working with the appropriate British Association for Sexual Health and HIV (BASHH) Special Interest Group (SIG) and the BASHH audit group.

Patients' views and preferences are sought and considered and the process documented. This may include patient representative involvement in the writing committee, information obtained from patient interview or surveys during the writing and/or piloting process, reviewing published work on patient experiences or involving patient associations. The chair of the writing group identifies an appropriate member such as the Health Advisor to get patient feedback on the guideline. BASHH is currently developing a public panel to assist with its work and in the future this group could be approached to assist in guideline development.

Recommendations are formulated with consideration of their health benefits, side effects and risks, with evidence presented in the guideline that these issues have been addressed. Each recommendation is linked to the supporting evidence with a list of relevant references.

Consideration is given to pragmatic and organisational issues relevant to the guideline. This is sought during and may emerge from the piloting of the guideline.

The authors consider the financial cost implications of recommendations made. Where disagreement arises within the writing committee with regard to recommendations the chair attempts to resolve these (for example by a voting system or formal consensus method). The process is documented and reported to the CEG editor. When this is not possible the CEG will review the evidence.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations

A (Evidence Levels Ia, Ib)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Clinical Validation-Pilot Testing

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Piloting and Feedback

The initial draft of the guideline, including the patient information leaflet (PIL) was piloted for validation by the Clinical Effectiveness Group (CEG). A standardised feedback form was completed by each pilot site for the patient information leaflet.

The final guideline was then reviewed by the Clinical Effectiveness Group (CEG) using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument before posting it on the British Association for Sexual Health and HIV (BASHH) website for external peer review for a 3 month period. Comments received were collated by the CEG editor and sent to the guideline chair for review and action. The final guideline was approved by the CEG and a review date agreed before publication on the BASHH website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is graded and identified for select recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate treatment of bacterial vaginosis (BV)

Potential Harms

- With metronidazole treatment alcohol should be avoided because of the possibility of a disulfiram-like action. There are no data on the risks from consuming alcohol with intravaginal metronidazole gel, but it is not recommended at present.
- Clindamycin cream can weaken condoms, which should not be used during such treatment. Pseudomembranous colitis has been reported

with both oral clindamycin and clindamycin cream.
- Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breast feeding. Small amounts of clindamycin enter breast milk.

Qualifying Statements

Qualifying Statements

Qualifying Statements

The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and available resources. All possible care has been undertaken to ensure the publication of the correct dosage of medication and route of administration. However, it remains the responsibility of the prescribing physician to ensure the accuracy and appropriateness of the medication they prescribe.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH). National guideline for the management of bacterial vaginosis. London (UK): British Association for Sexual Health and HIV (BASHH); 2012. 15 p. [43 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 Aug (revised 2012)

Guideline Developer(s)

British Association for Sexual Health and HIV - Medical Specialty Society

Source(s) of Funding

This guideline was commissioned, edited and endorsed by the British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Group (CEG) without external funding being sought or obtained.

Guideline Committee

Clinical Effectiveness Group (CEG)

Composition of Group That Authored the Guideline

Guideline Development Group: Dr. Phillip Hay MBBS FRCP (*lead author*), Dr Sheel Patel and Dr David Daniels (*Clinical Effectiveness Group lead*)

Clinical Effectiveness Group Members: Dr Keith Radcliffe (*Chair*); Consultant Physician in Genitourinary Medicine, Whittall Street Clinic; Dr David Daniels, West Middlesex University Hospitals NHS Trust, Sexual Health Clinic, West Middlesex Hospital; Dr Mark FitzGerald, Consultant Physician in Genitourinary Medicine, Musgrove Park Hospital; Dr Margaret Kingston, Consultant Physician in GU Medicine, Manchester Centre for Sexual Health, The Hathersage Centre; Dr Neil Lazaro, Associate Specialist in GU Medicine, Royal Preston Hospital; Dr Gill McCarthy, Consultant Physician in GU Medicine, Kingston Hospital NHS Trust, Wolverton Centre for Sexual Health; Dr Ann Sullivan, Consultant Physician in Genitourinary Medicine, Chelsea & Westminster Healthcare NHS Trust, John Hunter Clinic

Financial Disclosures/Conflicts of Interest

Declarations of Interest

All members of the guideline writing committee completed the British Association for Sexual Health and HIV (BASHH) conflict of interest declaration detailed below at the time the guideline's final draft was submitted to the Clinical Effectiveness Group.

D. Phillip Hay has received payment for research conducted in his unit, sponsorship to attend conferences, fees for consultancy from Bayer pharmaceuticals PLC, BBI Healthcare, Unipath, Pharmacia and Upjohn, 3M pharmaceuticals.

Guideline Status

This is the current release of the guideline.

This guideline updates a previously released version: Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH). National guideline for the management of bacterial vaginosis. London (UK): British Association for Sexual Health and HIV (BASHH); 2006. 14 p. [40 references]

Guideline Availability

Electronic copies: Available from the British Association for Sexual Health and HIV Web site .

Availability of Companion Documents

The following is available:

- Clinical Effectiveness Group. British Association for Sexual Health and HIV: framework for guideline development and assessment. London (UK): British Association for Sexual Health and HIV (BASHH); 2010. 18 p. Electronic copies: Available from the British Association for Sexual Health and HIV Web site .

Additionally, auditable outcome measures are available in the original guideline document .

Patient Resources

None provided

NGC Status

This summary was completed by ECRI on June 15, 2000. The information was verified by the guideline developer on October 13, 2000. This summary was updated by ECRI on June 24, 2002. This NGC summary was updated by ECRI Institute on December 12, 2007. The updated information was verified by the guideline developer on February 7, 2008. This NGC summary was updated by ECRI Institute on July 17, 2012.

Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developers and/or BMJ Publishing Group's copyright restrictions. Reproduction and use of this guideline is permitted provided that (a) the original content is not changed or edited; and, (b) any content derived from the original guideline is acknowledged as that of the author(s) and responsible organizations.

Readers wishing to download and reproduce material for purposes other than personal study or education should contact BMJPG to seek permission first. Contact: BMJ Publishing Group, BMA House, Tavistock Square, WC1H 9JR, UK.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.